

**REMARKS**

This amendment is submitted in response to the Office Action mailed March 25, 2008 in connection with the above-identified application (hereinafter, the "Office Action"). The Office Action provided a three-month shortened statutory period in which to respond, ending on June 25, 2008. Submitted herewith is a *Petition for a One-Month Extension of Time* extending the due date to July 25, 2008. Accordingly, this amendment is timely submitted.

**I. The Pending Claims**

Claims 1, 5-8, 10-11 and 26, of which claim 1 is independent, remain pending. Claims 2-4, 9, and 12-25 have been cancelled. New claim 27 is added and recites one of the features of the claimed invention. Applicant reserves the right to pursue these claims in a divisional or continuation application. Applicant respectfully submits that no new matter has been introduced by these amendments and in the introduction of the new claim. Thus, they all should be entered at this time.

Applicant does not acquiesce in the correctness of the rejections or objections and reserves the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further, Applicant reserves the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

As amended, independent claim 1 now recites a composition comprising an oligosaccharide blend that comprises FOS and GOS, wherein (a) a daily dosage of said oligosaccharide blend is about 25 g; (b) each of said oligofructose and oligogalactose are composed of chains with a degree of polymerization ranging from about 2 to about 7; (c) the weight ratio of FOS and GOS is from about 0.5 to about 20; and (d) the FOS and GOS are capable of synergistically promoting the growth of *Lactobacilli*, such that their combined prebiotic property is greater than the a sum of their individual prebiotic properties.

Amended claim 5, dependent on claim 1, is directed to a composition, wherein the daily dosage of the oligosaccharide blend is about 20 g or 15 g.

Support for the above-mentioned amendments is found at page 3, paragraphs [0040]-[0041] of the instant published patent application (U.S. Patent Application Publication No. 2004/0131659 A1).

New claim 27 is directed to a composition, recites some of the features of amended claim 1 but also recites that the oligosaccharide blend consists essentially of fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS), wherein each of said FOS and said GOS contains up to 95% by weight of said oligofructose and said oligogalactose. Support for the new claim is found at page 4, paragraph [0047] of the published patent application.

Applicant respectfully submits that the rejections based on lack of obviousness are overcome in view of the amendments and arguments presented in the response. Accordingly, entry of these amendments is requested.

## **II. Rejection Under 35 U.S.C §103(a)**

The Office Action rejected claims 1, 5-8 and 10-11 under 35 U.S.C. §103(a), as being unpatentable over U.S. Patent No. 6,399,124 B1 to Lesens et al. However, Applicant respectfully disagrees with the rejection for the reasons provided hereinbelow.

Applicant respectfully submits that Lesens neither describes nor suggests the presently-claimed compositions, as set forth in amended claim 1 and the claims that depend therefrom, as well as in new independent claim 27.

At the outset, the claimed invention, as set forth in amended independent claim 1, is drawn to a composition that includes an oligosaccharide blend that comprises FOS and GOS, wherein (a) a daily dosage of said oligosaccharide blend is about 25 g; (b) each of said oligofructose and oligogalactose are composed of chains with a degree of polymerization ranging from about 2 to about 7; (c) the weight ratio of FOS and GOS is from about 0.5 to about 20; and (d) the FOS and GOS are capable of synergistically promoting the growth of *Lactobacilli*, such that their combined prebiotic property is greater than the a sum of their individual prebiotic properties. New independent claim 27 recites that the oligosaccharide blend of the claimed composition "consists essentially of FOS and GOS, wherein each of said FOS and said GOS

contains up to 95% by weight of said oligofructose and said oligogalactose that are composed of chains with a degree of polymerization ranging from about 2 to about 7...."

Contrary to the claimed invention, Lesens generally describes and suggests frozen desserts that contain lactic acid bacteria and dietary fibers and its benefit to the human health after consumption of the frozen desserts. The maximum amount of fibers that make up the edible support of the frozen desserts is 10 g of fiber per dessert. According to Lesens, higher quantities of fibers would induce an unpleasant feeling of heaviness in the stomach. See Lesens at column 5, lines 23-29. The amount of fibers recommended by Lesens is lower than that of the claimed invention. Accordingly, Applicant respectfully submits that Lesens fails to disclose compositions containing a daily dosage of a combination of FOS and GOS that is about 25 g, 20 g or 15 g.

For the reasons provided hereinabove and claim amendments as presented herein, Applicant respectfully asserts that the composition of the presently claimed invention, drawn to amended independent claim 1 and dependent claims 5-8 and 10-11, as well as new claim 27, would not have been obvious to one of ordinary skill in the art. Lesens fails to describe or suggest a composition having an oligosaccharide blend of FOS and GOS, wherein the daily dosage of the oligosaccharide blend is between 15-25 g and a weight ratio FOS:GOS that is from about 0.5 to 20. Accordingly, Applicant respectfully requests that the Examiner to reconsider and withdraw her rejection of these claims under §103(a).

The Office Action has maintained its rejection of claims 1, 5, 7-8 and 10-11 under 35 U.S.C. §103(a), as being unpatentable over J. Pediatric Gastroenterology and Nutrition, Volume 34, pages 291-295 to Moro et al. (referred hereinafter as "Moro"); Arch. Dis. Child Fetal Neonatal. Ed., Volume 86, pages F178-F181, 2002 to Boehm et al. (referred hereinafter as "Boehm"); and Pediatrika, Vol. 21, Nov/Dec, pages 39-48, 2001 to Rigo et al. (referred hereinafter as "Rigo"), all in view of Lesens. Applicant respectfully disagrees with these rejections.

The disclosures of Lesens and the claimed invention are discussed above and are incorporated herein. As previously stated in the last response and as remarked hereinabove, Lesens fails to anticipate and render obvious the claimed invention because it fails to recite or suggest all the features of the present invention, as claimed. In addition, Applicant respectfully

submits that Moro, Boehm, Rigo and Lesens, either viewed individually or in any combination, all fail to disclose or suggest a composition that encompasses the subject matter as set forth in amended claim 1, as well as the claims that are dependent therefrom and new claim 27.

The Moro and Boehm references share three common authors, disclosed similar findings and were published around the same period by the same scientific institution. Both Moro and Boehm studied the bifidogenic effects of an oligosaccharide mixture on faecal flora and stool characteristics of preterm infants. To do this, an oligosaccharide mixture consisting of 90% GOS and 10% FOS was supplemented into a standard pre-term infant formula at a concentration of 10 g/L. The object of combining the oligosaccharide mixture and the pre-term infant formula by Moro and Boehm is to "mimic the molecular size distribution of human milk oligosaccharides" and to "benefit from a possible synergistic effect of both [FOS and GOS] compounds to stimulate the growth of *Bifidobacteria*." Moro at page 292. While Moro, Boehm and Rigo aimed to mimic the contents of breast milk, Lesens, on the other hand, intended her frozen dessert composition to promote the growth of beneficial gastrointestinal bacteria.

In addition, like Lesens, the three secondary references all fail to recite the required features of the claimed invention, i.e., a composition containing a daily dosage of a combination of FOS and GOS that is about 25 g, 20 g or 15 g and the weight ratio of FOS and GOS is from about 0.5 to about 20 and wherein the FOS and GOS are capable of synergistically promoting the growth of *Lactobacilli*, such that their combined prebiotic property is greater than the a sum of their individual prebiotic properties.

In Moro, while noting the possibility of a synergistic effect of FOS and GOS, reported results that do not support such an effect on *Lactobacilli*. The number of *Lactobacilli* also increased significantly in both groups fed the supplemented formulas (versus placebo,  $P < 0.001$ ), but there was no statistically significant difference between the group fed formula with 0.4g/dL oligosaccharides and the group fed formula with 0.8 g/dL oligosaccharides." See Moro's Abstract.

With respect with Boehm, the results obtained support the lack of a synergistic effect. "*Lactobacilli* were also detectable in all infants at the study entry. There was a significant increase in all groups during the course of the study period but there was no significant effect on the diet (data not shown). Neither was there a significant effect of the oligosaccharide

supplement on the counts of *Bacteroides*, *Clostridium* species, *E. coli*, *Enterobacter*, *Citrobacter*, *Proteus*, *Klebsiella*, and *Candida*. Boehm at page F180, left column, third full paragraph.

In Rigo, the growth and quality of growth of term infants fed with a New Formula (NF) were similar to those seen in infants that were fed with breast fed and conventional formulas. The composition of the New Formula includes prebiotic substances such as FOS and GOS wherein the total amount together is 0.4 g/100 ml; partially hydrolyzed whey protein and  $\beta$ -palmitate. According to Rigo, the "use of prebiotic substances in NF resulted in a rapid and significant increase in the percentage of endogenous bifidobacteria and the ability to maintain a stable intestinal flora during the first months of age." Rigo at page 39.

Therefore, like Lesens, the three secondary references, Moro, Boehm and Rigo, all fail to suggest the use of the presently-claimed composition having all the required features, as recited in amended claim 1, as well as in the claims that depend therefrom and including new independent claim 27.

Based on the remarks presented hereinabove and in light of the claim amendments herein, Applicant respectfully submits that Moro, Boehm, Rigo and Lesens, either individually or in combination, fail to render claims 1, 5, 7-8 and 10-11 obvious. Accordingly, Applicant earnestly requests the Examiner to reconsider and withdraw the rejection of these claims based on Moro, Boehm, Rigo, in view of Lesens.

Claims 1 and 26 remain rejected under 35 U.S.C. §103(a), as being unpatentable over Lesens, in view of U.S. Patent Application Publication No. US2003/0138476A1 to Van Leeuwen et al. (referred hereinafter as "Van Leeuwen").

Applicant respectfully submits that Lesens and Van Leeuwen, either taken individually or in combination, fail to disclose or suggest the claimed composition as set forth in amended claims 1 and 26. More specifically, Lesens and Van Leeuwen fail to disclose or suggest a composition that contains an a composition that includes a daily dosage of FOS and GOS blend that is about 25 g, 20 g. or 15 g and the weight ratio of FOS and GOS is from about 0.5 to about 20 and wherein the FOS and GOS are capable of synergistically promoting the growth of

*Lactobacilli*, such that their combined prebiotic property is greater than the a sum of their individual prebiotic properties.

The disclosures of Lesens and the claimed invention are both discussed in the above-mentioned sections.

Van Leeuwen's invention relates to the "use of glutamic acid for the preparation of a nutritional preparation that is intended for use for the treatment or prevention of excess or undesired permeability of the intestinal wall. See Van Leeuwen's Abstract. The nutritional preparation can be "combined with suitable prebiotics and probiotics, which have a beneficial effect on the intestinal flora. The prebiotics comprise short or long chain oligosaccharides, in particular galacto-oligosaccharides and fructo-oligosaccharides...." Van Leeuwen at page 2, paragraph [0017]. However, Van Leeuwen, similar to Lesens, fails to disclose a composition containing a daily dosage of a combination of FOS and GOS that is about 25 g, 20 g or 15 g and wherein the weight ratio of FOS and GOS is from about 0.5 to about 20, the subject matter of which is encompassed in amended claims 1 and 27. Van Leeuwen, as well as Lesens, also fails to suggest a synergistic effect of FOS and GOS on the growth of *Lactobacilli*, such that their combined prebiotic property is greater than the sum of their individual prebiotic properties. Accordingly, Van Leeuwen fails to cure the deficiency of Lesens to enable one of the ordinary skill in the art to make or use the claimed composition of the present invention. Moreover, even if Van Leeuwen is combined with Lesens, one of ordinary skill in the art would still not arrive at the claimed composition because both of these references fail to disclose or suggest the claimed composition as set forth in both amended claims 1 and 26. See MPEP 2143.03 ("To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art").

Furthermore, Applicant respectfully submits that the Office Action has failed to establish any motivation to combine Lesens and Van Leeuwen. The Federal Circuit has repeatedly emphasized that evidence of a motivation to combine must accompany a challenge based on multiple references. See *In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999) and *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534 (Fed. Cir. 1998). See also MPEP §2143.01 (The prior art must suggest the desirability of the claimed invention). A statement that combination of the prior art

to meet the claimed invention would have been within the ordinary skill in the art is not alone sufficient to establish a prima facie case of obviousness.

Accordingly, Applicant respectfully submits that claims 1 and 26 are not obvious over Lesens and Van Leeuwen. Applicant earnestly requests the Examiner to reconsider and withdraw the rejection of these claims under § 103(a).

In light of the amendments and remarks presented hereinabove, Applicant respectfully submits that the rejections based on lack of obviousness have been overcome. Applicant earnestly requests the Examiner to reconsider and withdraw all of her rejections based on 35 U.S.C. §103(a).

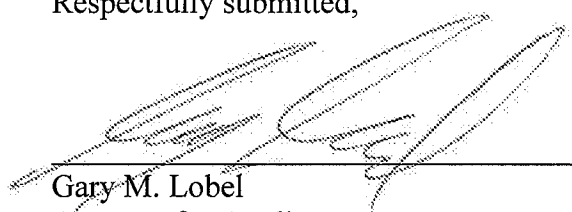
### **CONCLUSION**

For at least the reasons set forth above, this application is in condition for allowance. Favorable consideration and prompt allowance of the claims are earnestly requested. Should the Examiner have any questions that would facilitate further prosecution or allowance of this application, the Examiner is invited to contact the Applicant's representative designated below.

The Commissioner is hereby authorized to charge any additional fees under 37 CFR §1.17 which may be required, or credit any overpayment, to deposit account no. 50-4498 in the name of Nestlé Nutrition.

Respectfully submitted,

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